Aravive Announces Positive Preliminary Data from Phase 1b Trial Evaluating Batiraxcept (AVB-500) in Combination with Cabozantinib for Treatment of Clear Cell Renal Cell Carcinoma

November 12, 2021

7 of 16 (44%) patients achieved best overall response of partial response
Confirmed response in 5 of 7 (71%) patients who had at least 16 weeks of follow-up
14 of 16 (88%) patients demonstrated tumor decrease from baseline
Batiraxcept has been well-tolerated with no dose-limiting toxicities
Conference call and webcast today at 8:30 a.m. ET

HOUSTON, Nov. 12, 2021 (GLOBE NEWSWIRE) -- Aravive, Inc. (Nasdaq: ARAV), a clinical-stage oncology company developing transformative, targeted therapeutics to treat life-threatening cancers, today announced positive new data from the Phase 1b portion of its open-label Phase 1b/2 trial evaluating batiraxcept (AVB-500) in combination with cabozantinib in patients with clear cell renal cell carcinoma (ccRCC). A subset of these data was included in a poster presentation at the Society for Immunotherapy of Cancer's (SITC) 36 th Annual Meeting being held November 10-14, 2021.

"We are encouraged by batiraxcept's early profile in patients with clear cell renal cell carcinoma," said Gail McIntyre, Ph.D., DABT, Chief Executive Officer of Aravive. "The current response rate of batiraxcept in combination with cabozantinib is encouraging. Cabozantinib alone produces response rates between 17-28% in a similar population. In heavily pretreated patients, batiraxcept demonstrates clinical activity across the 15 mg/kg and 20 mg/kg doses with a tolerable safety profile. These results reinforce our confidence in the potential of batiraxcept to improve outcomes across multiple types of cancer by targeting the GAS6/AXL signaling pathway. We look forward to initiating the Phase 2 trial in the fourth quarter of 2021 and building on these promising data."

As of November 9, 2021, the safety, pharmacokinetics (PK), and pharmacodynamics (PD) of batiraxcept 15 mg/kg and 20 mg/kg in combination with cabozantinib in patients with 2L+ ccRCC have been evaluated in 18 patients. Clinical activity across these two doses has been evaluated in 16 patients.

Safety Data:

- Analysis of all safety data demonstrates that batiraxcept has been well-tolerated with no dose-limiting toxicities.
- There have been no batiraxcept-related serious adverse events reported to date.
- There were no batiraxcept-related Grade 4 or 5 adverse events.
- 3 patients experienced Grade 3 adverse events considered by the investigator as potentially being related to both batiraxcept and cabozantinib.
    - At the batiraxcept 15 mg/kg dose, 1 patient experienced transient hypertension and 1 patient experienced transient thrombocytopenia. Both events resolved while still receiving batiraxcept.
    - At the batiraxcept 20 mg/kg dose, 1 patient experienced a thromboembolic event, small bowel obstruction, abdominal pain and vomiting. The bowel obstruction, abdominal pain and vomiting resolved while the patient continued batiraxcept treatment.
    - All events are known adverse events associated with cabozantinib use.

PK/PD Data:

- PK analyses indicate that batiraxcept trough levels were above the minimally efficacious concentration (MEC) of 13.8 mg/L prior to cycle 2 day 1 in the first 10 efficacy-evaluable patients.

Clinical Activity Data:

- Best overall response of partial response was observed in 7 of 16 (44%) evaluable patients across both dose levels. 9 of 16 (56%) patients had a best overall response of stable disease. No patients had progressive disease at their first radiological exam.
- 7 of 16 patients have had at least 16 weeks of follow up (at least two post-baseline radiological exams). 5 of the 7 (71%) patients have confirmed partial responses and 2 of the 7 (29%) patients achieved confirmed stable disease.
- 88% (14/16) of patients had tumor decrease from baseline.
- 4 patients had 1 or more target lesions completely disappear. 3 patients were treated with batiraxcept 15 mg/kg and cabozantinib and 1 patient was treated with batiraxcept 20 mg/kg and cabozantinib.
- 2 patients had target lesions decrease from baseline by more than 76%. 1 patient was treated with batiraxcept 15 mg/kg and 1 patient was treated with batiraxcept 20 mg/kg.
- This clinical activity was observed despite cabozantinib dose reductions with median cabozantinib dose intensity of 41 mg (68% of 60 mg prescribed dose).

“The initial Phase 1b data of batiraxcept in combination with cabozantinib are impressive and point toward the role of dual AXL and VEGF inhibition in the treatment of clear cell renal cell carcinoma,” said Eric Jonasch, M.D., Professor of Medicine, The University of Texas MD Anderson Cancer Center. “These early signs of clinical activity coupled with a manageable safety profile introduce a potential new therapeutic approach for patients with advanced kidney cancer.”

Poster Presentation Details

Title:	A Phase 1b/2 randomized study of AVB-S6-500 in combination with cabozantinib versus cabozantinib alone in patients with advanced clear cell renal cell carcinoma who have received front-line treatment
Presenter:	Reshma Rangwala, M.D., Ph.D., Chief Medical Officer of Aravive
Date:	November 13, 2021
Time:	7:00 a.m. – 8:30 p.m. ET
Location:	Hall E

For additional information, please visit the SITC 36th Annual Meeting website: https://www.sitcancer.org/2021/home.

Conference Call Information
Aravive will host a conference call and webcast today, November 12, 2021, at 8:30 a.m. ET to discuss these clinical data. The conference call may be accessed by dialing (877) 423-9813 (domestic) and (201) 689-8573 (international) and referring to conference ID 13724115. A webcast of the conference call will be available in the Investors section of the Aravive website at https://ir.aravive.com/. The archived webcast will be available on Aravive’s website after the conference call.

About the Batiraxcept (AVB-500) Phase 1b/2 ccRCC Trial
The Phase 1b portion of the clinical trial is expected to enroll approximately 25 patients in two dosing parts (15 mg/kg and 20 mg/kg) to evaluate tolerability, PK, PD, and clinical activity of batiraxcept in combination with cabozantinib. The open-label Phase 2 portion of the clinical trial is expected to enroll 55 patients across three parts. Part A is expected to enroll approximately 25 patients and investigate batiraxcept 15 mg/kg in combination with cabozantinib in 2L+ ccRCC patients. Part B is expected to enroll approximately 20 patients and evaluate batiraxcept 15 mg/kg in combination with nivolumab and cabozantinib as a potential front-line treatment for ccRCC. Part C is expected to evaluate batiraxcept 15 mg/kg monotherapy in approximately 10 patients with ccRCC who are not eligible for curative intent therapies.

About Batiraxcept (AVB-500)
Batiraxcept is a therapeutic recombinant fusion protein that has been shown to neutralize GAS6 activity by binding to GAS6 with very high affinity in preclinical models. In doing so, batiraxcept selectively inhibits the GAS6-AXL signaling pathway, which is upregulated in multiple cancer types including ovarian, renal and pancreatic cancer. In preclinical studies, GAS6-AXL inhibition has shown anti-tumor activity in combination with a variety of anticancer therapies, including radiation therapy, immuno-oncology agents, and chemotherapeutic drugs that affect DNA replication and repair. Increased expression of AXL and GAS6 in tumors has been correlated with poor prognosis and decreased survival and has been implicated in therapeutic resistance to conventional chemotherapeutics and targeted therapies. Batiraxcept is currently being evaluated in multiple clinical trials and has been granted Fast Track designation by the U.S. Food and Drug Administration and orphan drug designation by the European Commission in platinum resistant recurrent ovarian cancer.

About Aravive
Aravive, Inc. is a clinical-stage oncology company developing transformative, targeted therapeutics to treat life-threatening cancers. The Company is currently evaluating its lead therapeutic, batiraxcept (AVB-500), in a registrational Phase 3 trial in platinum resistant ovarian cancer, a Phase 1b/2 trial in second line plus, clear cell renal cell carcinoma, and a Phase 1b/2 trial in first-line treatment of pancreatic adenocarcinoma. The Company is based in Houston, Texas and received a Product Development Award from the Cancer Prevention & Research Institute of Texas (CPRIT) in 2016. For more information, please visit www.aravive.com.

Forward-Looking Statements
This communication contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases, forward-looking statements can be identified by terminology such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," and similar expressions and includes statements regarding the potential of batiraxcept (AVB-500) to improve outcomes for patients with advanced kidney cancer and the expected enrollment in the Phase 1b and Phase 2 trial portions of the ccRCC trial. Forward-looking statements are based on current beliefs and assumptions, are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from those contained in any forward-looking statement as a result of various factors, including, but not limited to, risks and uncertainties related to: the potential of batiraxcept as a new therapeutic approach for patients with advanced kidney cancer, the data from patients treated in the future with batiraxcept being consistent with the results reported, the ability to enroll the expected number of patients, the impact of COVID-19 on the Company's clinical strategy, clinical trials, supply chain and fundraising, the Company's ability to expand development into additional indications, the Company's dependence upon batiraxcept, batiraxcept’s ability to have favorable results in clinical trials and ISTs, the clinical trials of batiraxcept having results that are as favorable as those of preclinical and clinical trials, the ability to receive regulatory approval, potential delays in the Company's clinical trials due to regulatory requirements or difficulty identifying qualified investigators or enrolling patients especially in light of the COVID-19 pandemic; the risk that batiraxcept may cause serious side effects or have properties that delay or prevent regulatory approval or limit its commercial potential; the risk that the Company may encounter difficulties in manufacturing batiraxcept; if batiraxcept is approved, risks associated with its market acceptance, including pricing and reimbursement; potential difficulties enforcing the Company's intellectual property rights; the Company's reliance on its licensor of intellectual property and financing needs. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020, recent Current Reports on Form 8-K and subsequent filings with the SEC. Except as required by applicable law, the Company undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information,

future events or otherwise.

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